UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

SABBY VOLATILITY WARRANT MASTER FUND LTD., EMPERY ASSET MASTER, LTD, EMPERY TAX EFFICIENT, LP, EMPERY TAX EFFICIENT III, LP Plaintiffs, v. KIROMIC BIOPHARMA, INC., MAURIZIO CHIRIVA-INTERNATI, TONY TONTAT, GIANLUCA ROTINO, PIETRO BERSANI, AMERICO CICCHETTI, MICHAEL NAGEL, JERRY SCHNEIDER and THINKEQUITY LLC, Defendants.	Civil Action No. 1:22-cv-01927 **FIRST AMENDED COMPLAINT** **JURY TRIAL DEMANDED**

COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS

Plaintiffs Sabby Volatility Warrant Master Fund Ltd. ("Sabby"), Empery Asset Master, Ltd. ("Empery Master"), Empery Tax Efficient, LP ("Empery Tax"), and Empery Tax Efficient III, LP ("Empery Tax III," together with Empery Master and Empery Tax, the "Empery Entities"), collectively "Plaintiffs," by and through their counsel, respectfully allege, upon knowledge as to their own acts and upon information and belief as to the acts of others, as follows:

INTRODUCTION

1. Plaintiffs assert claims under the Securities Act of 1933 (the "1933 Act") arising from a public offering of common stock by Kiromic BioPharma, Inc. ("Kiromic"). The public

offering closed on July 2, 2021 (the "Offering") and was conducted pursuant to a registration statement filed with the SEC on June 25, 2021 ("Registration Statement") and a final prospectus dated June 29, 2021 (the "Prospectus," with the Registration Statement, the "Offering Documents").

2. Sabby purchased 500,000 shares priced at $5.00 per share through the Offering, for a total investment of $2.5 million. The Empery Entities purchased an aggregate of 1,000,000 shares priced at $5.00 per share through the Offering, for a total investment of $5 million. At the time of the Offering, Kiromic presented itself as a target discovery and gene-editing company which utilized artificial intelligence to create immunotherapy products. While Kiromic had no immunotherapy products on the market at the time, it had applications to begin human clinical trials for two new drug candidates, known as Investigational New Drug ("IND") applications, pending with the Food and Drug Administration ("FDA"). The Offering Documents stated that Kiromic could commence clinical trials within 30 days of those IND applications unless the FDA imposed a clinical hold.

3. A clinical hold is an order issued by the FDA to delay or suspend new or existing clinical trials with respect to an applicant's products. When a proposed study is placed on clinical hold, no new subjects may be recruited for testing the drug, and patients already testing the drug must be taken off. A clinical hold can be imposed, among other grounds, where "(i) [h]uman subjects are or would be exposed to an unreasonable and significant risk of illness or injury; (ii) [t]he clinical investigators named in the IND are not qualified by reason of their scientific training and experience to conduct the investigation described in the IND; (iii) [t]he investigator brochure is misleading, erroneous, or materially incomplete. . . ."

4. The Offering Documents did not mention that the FDA had, prior to the filing of the Prospectus and Registration Statement, imposed a clinical hold, and in fact, contained statements indicating that it had not. Given that the Offering closed on July 2, 2021, more than 30 days after Kiromic submitted the IND applications for its two immunotherapy product candidates, investors were assured that no clinical hold had been issued and clinical trials could commence.

5. Kiromic, however, had received communications from the FDA on June 16 and 17, 2021, informing it that the FDA was placing the IND applications for its two candidate products on clinical hold. The Offering Documents failed to disclose this information, instead representing that clinical testing was expected to proceed in the third quarter of 2021. Clinical testing did not proceed in the third quarter of 2021, nor was it likely given the FDA's imposition of a clinical hold.

6. The significant price drop that occurred immediately following a July 16, 2021 press release through which Kiromic disclosed that it had received "comments" from the FDA clearly demonstrates the materiality of this information.

7. Thus, the Offering Documents contained untrue statements of material fact, omitted material facts necessary to make the statements contained in them not misleading, and/or failed to make adequate disclosures otherwise required regarding the status of those applications. These errors did not arise from a fraudulent scheme, but rather from severe errors in judgment as to the materiality of the FDA Communications in the context of the voluminous prospectus. Upon information and belief, some of the defendants also failed to review the prospectus with care to assure that its contents were complete and accurate.

8. As a result of these untrue and misleading statements and omissions, and the resulting decline in the market value of Kiromic's stock, Plaintiffs have suffered significant losses and damages.

JURISDICTION AND VENUE

9. The claims asserted in this Complaint arise under Sections 11, 12(a)(2), and 15 of the Securities Act (15 U.S.C. §§ 77k, 77l(a)(2), and 77o).

10. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1337 and Section 22 of the Securities Act (15 U.S.C. § 77v).

11. This Court has personal jurisdiction over the Defendants because this action arises under federal law, and Section 22 of the Securities Act (15 U.S.C. § 77v) authorizes nationwide service of process. All Defendants have sufficient contacts with the United States. Kiromic is a Delaware corporation with its principal place of business in Houston, Texas, whose shares trade on the Nasdaq Capital Market, a New York stock exchange. ThinkEquity LLC ("ThinkEquity"), maintains its offices at 17 State Street, New York, NY 10004. All Individual Defendants are directors or officers of Kiromic. All Individual Defendants signed the Registration Statement, which they knew was prepared pursuant to the securities laws of the United States, for the purpose of an offering which took place in New York, and which was filed with the SEC. Moreover, Maurizio Chiriva-Internati, Pietro Bersani, Michael Nagel, and Jerry Schneider reside in the United States. Gianluca Rotino has traveled to the United States on multiple instances for work related to his position at Kiromic, and signed an employment agreement with Kiromic designating the United States as the forum for any dispute arising out of the agreement. Similarly, Tony Tontat signed an employment agreement with Kiromic designating the United States as the forum for any dispute arising out of the agreement. Americo Cicchetti is a visiting

scholar at a United States medical school, Thomas Jefferson University, located in Woodbury, New Jersey.

12. Venue is proper in this District under 28 U.S.C. § 1391(b) and Section 22 of the Securities Act (15 U.S.C. § 77v). The Offering was underwritten by ThinkEquity, which maintains its offices at 17 State Street, New York, NY 10004. Plaintiffs purchased the shares underlying this action as part of the Offering through ThinkEquity. Therefore, this is the proper venue as the district where the offer or sale of the securities underlying this action took place, which Kiromic participated in as the issuer.

PARTIES

13. Plaintiff Sabby Volatility Warrant Master Fund Ltd. is a company formed under the laws of the Cayman Islands.

14. Plaintiff Empery Asset Master, Ltd. is a company organized under the laws of the Cayman Islands.

15. Plaintiff Empery Tax Efficient, LP is a limited partnership organized under the laws of Delaware.

16. Plaintiff Empery Tax Efficient III, LP is a limited partnership organized under the laws of Delaware.

17. Defendant Kiromic BioPharma, Inc. is a Delaware corporation with its principal place of business in Houston, Texas. Kiromic's shares trade on the Nasdaq Capital Market under the symbol "KRBP." Kiromic signed the Registration Statement through its Chief Executive Officer, Maurizio Chiriva-Internati.

18. Defendant ThinkEquity LLC is a Delaware limited liability company with its principal place of business at 17 State Street, New York, NY 10004. ThinkEquity is successor to Fordham Financial Management Inc. ("FFA"), which was the underwriter, and was listed as such

in the Offering Documents. FFA converted to a limited liability company and changed its name on August 21, 2021.

19. Defendant Maurizio Chiriva-Internati served, at times relevant to the claims alleged in this Complaint, as Kiromic's Chief Executive Officer and signed the Registration Statement either personally or by attorney-in-fact. As of June 25, 2021, Mr. Chiriva-Internati beneficially owned 18.61% of Kiromic's common stock. Mr. Chiriva-Internati served as Kiromic's Chief Scientific Officer from December 2012 to September 2019 and has PhDs in Immunology, Morphological Science, and Biological Sciences.

20. Defendant Tony Tontat served, at times relevant to the claims alleged in this Complaint, as Kiromic's Chief Financial Officer and signed the Registration Statement either personally or by attorney-in-fact. As of June 25, 2021, Mr. Tontat beneficially owned 6.10% of Kiromic's common stock.

21. Defendant Gianluca Rotino served, at times relevant to the claims alleged in this Complaint, as Kiromic's Chief Strategy and Innovation Officer and signed the Registration Statement either personally or by attorney-in-fact. As of June 25, 2021, Mr. Rotino beneficially owned 6.21% of Kiromic's common stock. Mr. Rotino has "completed course work for drug discovery, development and commercialization provided by The University of California San Diego, Skaggs School of Pharmacy and Pharmaceutical Sciences Drug Development."

22. Defendant Pietro Bersani served, at times relevant to the claims alleged in this Complaint, as one of Kiromic's Directors and chair of Kiromic's audit committee. Mr. Bersani signed the Registration Statement either personally or by attorney-in-fact. Mr. Bersani is currently the CEO of Kiromic.

23. Defendant Americo Cicchetti served, at times relevant to the claims alleged in this Complaint, as one of Kiromic's Directors and signed the Registration Statement either personally or by attorney-in-fact.

24. Defendant Michael Nagel served, at times relevant to the claims alleged in this Complaint, as one of Kiromic's Directors and a member of Kiromic's audit committee. Mr. Nagel signed the Registration Statement either personally or by attorney-in-fact. Mr. Nagel "has over 30 years of sales and marketing experience in the medical device industry" and was selected to serve on Kiromic's board of directors for his industry experience.

25. Defendant Jerry Schneider served, at times relevant to the claims alleged in this Complaint, as one of Kiromic's Directors and a member of Kiromic's audit committee. Mr. Schneider signed the Registration Statement either personally or by attorney-in-fact.

26. Maurizio Chiriva-Internati, Tony Tontat, Gianluca Rotino, Pietro Bersani, Americo Cicchetti, Michael Nagel, and Jerry Schneider are collectively referred to in this Complaint as "Individual Defendants."

27. Kiromic, the Individual Defendants and ThinkEquity are collectively referred to in this Complaint as "Defendants."

FACTS GIVING RISE TO THIS ACTION

A. Background

28. Kiromic described itself to investors as a "target discovery and gene-editing company utilizing artificial intelligence and our proprietary neural network platform with a therapeutic focus on immuno-oncology." To generate revenue, Kiromic is dependent on the successful "development, regulatory approval and commercialization" of immunotherapy product candidates. As of June 29, 2021, Kiromic had no approved products, had not generated

any revenue, and continued to incur significant product and development expenses related to its ongoing operations.

B. The ALEXIS Products

29. As of June 29, 2021, Kiromic's only product candidates were a brand of immunotherapy products called ALEXIS-ISO-1 and ALEXIS-PRO-1 (collectively "ALEXIS"). As explained in the Offering Documents, the ALEXIS products are chimeric antigen receptor T cell (CAR-T) therapies "designed to treat cancer by capitalizing on the immune system's ability to destroy cancer cells." Such therapies have "recently emerged as a revolutionary and potentially curative therapy for patients with hematologic cancers, including refractory cancers."

30. Before the ALEXIS products could be sold, Kiromic needed to obtain regulatory approval from the FDA. In the Offering Documents, Kiromic explained to investors that the process required by the FDA before a biological product could be marketed in the United States generally involved. The following passage is taken directly from the Offering Documents:

- completion of nonclinical laboratory tests and animal studies according to good laboratory practices, or GLPs, and applicable requirements for the humane use of laboratory animals or other applicable regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- approval by an independent IRB or ethics committee at each clinical site before the trial is commenced;
- performance of adequate and well-controlled human clinical trials according to the FDA's GCPs, and any additional requirements for the protection of human research patients and their health information, to establish the safety and efficacy of the proposed biological product for its intended use;
- submission to the FDA of a BLA for marketing approval that includes substantial evidence of safety, purity, and potency from results of nonclinical testing and clinical trials;
- satisfactory completion of an FDA Advisory Committee review, if applicable;

- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the biological product is produced to assess compliance with cGMP, to assure that the facilities, methods and controls are adequate to preserve the biological product's identity, strength, quality and purity and, if applicable, the FDA's current good tissue practices, or GTPs, for the use of human cellular and tissue products;

- potential FDA audit of the nonclinical study and clinical trial sites that generated the data in support of the BLA; and

- FDA review and approval, or licensure, of the BLA.

31. Thus, before human clinical trials could commence, an applicant had to complete nonclinical laboratory tests and animal studies and submit to the FDA an IND application.

32. Kiromic explained in the Offering Documents that the IND application "automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions regarding the proposed clinical trials and places the trial on a clinical hold within that 30-day time period." In that event, the "IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin." If the FDA imposes a clinical hold, "*trials may not recommence without FDA authorization* and then only under terms authorized by the FDA." (emphasis added).

33. On December 17, 2020, Kiromic submitted two IND applications with the FDA for the ALEXIS products. After communicating with the FDA, Kiromic resubmitted these applications on May 14 and May 17, 2021. The revised IND applications were for human clinical trials of the ALEXIS products. The Offering Documents were otherwise silent regarding the status of the IND applications.

C. The FDA Communications

34. On June 16 and 17, 2021, Kiromic received communications from the FDA that the FDA was placing Kiromic's IND applications on clinical hold (the "FDA Communications"). The Offering Documents did not disclose this highly material information. The clinical hold had

broad-ranging implications for the IND applications, raising the possibility that clinical trials could be delayed indefinitely with substantial costs required to address FDA issues, or that the clinical hold might never be lifted.

35. The FDA IND Application Procedures explain that a "clinical hold order may be made by telephone or other means of rapid communication."

36. The FDA Communications were undoubtedly material to investors, had they been disclosed prior to the Offering. In fact, a significant price drop occurred immediately following Kiromic's July 16, 2021 press release disclosing that it had received "comments" from the FDA regarding the ALEXIS products. Sale of ALEXIS products, which would be impossible without FDA approval, provided Kiromic's only prospect for continuing to advance product candidates and for potentially generating revenue. The FDA Communications gave notice that Kiromic could not commence clinical trials as planned and might never do so. Indeed, clinical holds are rarely issued and the most common reasons for clinical holds are clinical and product quality issues. Many IND applications which are put on clinical hold remain on clinical hold for over a year. Addressing the issues raised by the FDA may come at great financial expense. A delay in clinical trials is, of course, detrimental to business operations by delaying access to much needed revenue with ever mounting expenses. Kiromic recognized this risk in the discussion of risk factors in the Offering Documents:

> If we experience termination of, or delays in the completion of, any clinical trial of our product candidates, the commercial prospects for our product candidates will be harmed, and our ability to generate product revenue will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenue.

37. The Offering Documents' discussion of risk factors emphasized that "[t]he clinical and commercial success of our current and any future product candidates will depend on a number of factors, including . . . **timely completion** of our preclinical studies and **clinical trials**. . . ." (emphasis added). Indeed, Kiromic listed four "principal factors" that might affect its financial performance, two of which were "slow or delayed IND applications," and "slow or delayed clinical trial enrollment."

38. The Offering Documents' discussion of risk factors emphasized the materiality of a clinical hold. It warned investors that:

- Clinical trials "may be suspended or terminated by . . . the FDA . . . due to a number of factors . . . resulting in the imposition of a clinical hold[;]"
- "[F]ailure to comply with regulatory requirements" may result in "holds on clinical trials;"
- "[T]he FDA can place an IND application on clinical hold even if such other [regulatory] entities have provided a favorable review[.]"

39. Moreover, information about the FDA Communications was also material to investors by signaling the FDA's likelihood to ultimately grant approval for commercialization of the ALEXIS products. As Kiromic recognized in the Offering Documents "[m]any of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may ultimately lead to the denial of regulatory approval of our product candidates."

40. If the ALEXIS products were unable to obtain regulatory approval, Kiromic recognized that the Company "may not be able to continue" operations.

41. Kiromic did not commence clinical trials in the third quarter of 2021 as planned, and to Plaintiffs' knowledge, Kiromic remains subject to the FDA's hold notice to this day.

D. The Offering

42. On June 29, 2021, Kiromic announced the pricing terms of a public offering to be closed on July 2, 2021. The offering resulted in the sale of 8,000,000 shares of Kiromic common stock at a price of $5.00 per share, for gross proceeds of $40 million. Kiromic announced the pricing of the Offering through a June 29, 2021 press release which listed the amount of shares offered, the price, directed the reader where to find the final prospectus, and explained that the shares of common stock "are being offered by" Kiromic. The press release also explained that Kiromic planned to use net proceeds "primarily for clinical trials for its ALEXIS-ISO-1 and ALEXIS-PRO-1 product candidates, GMP facility expansion, intellectual property protection and reinforcement, IND applications and IND enabling trials and working capital and the remainder for general corporate purposes." In light of the clinical holds, however, the proceeds of the Offering would have to be used to remedy the concerns expressed by the FDA. In fact, many of the uses listed would not be possible unless Kiromic was able to promptly resolve the clinical hold issues with the FDA.

43. The Offering was underwritten by ThinkEquity on a firm commitment basis. The Offering Documents explained that "[t]he underwriters are committed to purchase all shares offered by us" other than those covered by an over-allotment option.

44. Plaintiffs understood that the primary purpose of the offering was to generate cash to fund upcoming human clinical trials for the ALEXIS products.

45. The Offering was conducted pursuant to a registration statement filed with the SEC on June 25, 2021 ("Registration Statement") and a final prospectus dated June 29, 2021 (the "Prospectus," with the Registration Statement, the "Offering Documents"). The Offering Documents became effective on June 29, 2021.

46. The Registration Statement is substantially the same as a draft registration statement that Kiromic filed with the SEC on June 11, 2021. Kiromic was informed on June 17, 2021 that the SEC did not intend to review the draft registration statement.

47. Sabby participated in the Offering and received an allocation of 500,000 shares priced at $5.00 per share, for a total investment of $2.5 million. Sabby's purchase was issued pursuant and traceable to the Offering because Sabby purchased its shares directly in the Offering.

48. Empery Master participated in the Offering and received an allocation of 635,260 shares priced at $5.00 per share, for a total investment of $3,176,300. Empery Master's purchase was issued pursuant and traceable to the Offering because Empery Master purchased its shares directly in the Offering.

49. Empery Tax participated in the Offering and received an allocation of 177,550 shares priced at $5.00 per share, for a total investment of $887,750. Empery Tax's purchase was issued pursuant and traceable to the Offering because Empery Tax purchased its shares directly in the Offering.

50. Empery Tax III participated in the Offering and received an allocation of 187,190 shares priced at $5.00 per share, for a total investment of $935,950. Empery Tax III's purchase was issued pursuant and traceable to the Offering because Empery Tax III purchased its shares directly in the Offering.

E. Untrue and Misleading Statements in the Offering Documents[1]

51. The Offering Documents contained untrue statements of material fact, omitted material facts necessary to make the statements contained in them not misleading, and omitted to

[1] Unless otherwise stated, the untrue and misleading statements and omissions within the Offering Documents discussed in this Complaint are reflected in both the Registration Statement *and* the Prospectus.

state material facts required under the statute, rules, and regulations governing the preparation of public offering documents for securities.

52. In relevant part, the Offering Documents described the status of the ALEXIS products' applications to the FDA as follows:

> These products are in the pre-initial new drug ("IND") stages of the US Food and Drug Administration (the "FDA") clinical trial process. We are currently going through the IND enabling trials process and we expect that first in human dosing in Phase I of clinical trials will commence in the third quarter of 2021.

Disclosure of the FDA Communications informing Kiromic that their IND applications were put on clinical hold was necessary to make this statement not misleading because the imposition of a clinical hold is material information that a reasonable investor would have expected to be included in a description of the status of the ALEXIS IND applications. However, this information was not made public until after the Offering had closed.

53. Omission of the FDA Communications rendered this statement especially misleading in light of the Offering Documents' ambitious statement that human dosing in Phase I of clinical trials was expected to commence in the third quarter of 2021. With such an optimistic estimate, a reasonable investor would have been misled to believe that the FDA had not issued a clinical hold.

54. This is especially true given that the Offering Documents disclosed that when the ALEXIS IND applications were originally submitted on December 17, 2020, it took five months of communication with the FDA and consults with its scientific board and clinical advisors before Kiromic was able to resubmit those applications on May 14 and May 17, 2021. A reasonable investor would have concluded that the FDA had not provided further comments given that the commencement of clinical trials by the third quarter of 2021 would otherwise have been unrealistic or even impossible.

55. Moreover, by June 29, 2021 the requisite 30 day period for the FDA to provide comments before the IND applications would have become effective had elapsed, and a reasonable investor would have concluded that the clinical trials should have been able to commence. As Kiromic explained in the Offering Documents, the "IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions regarding the proposed clinical trials and places the trial on a clinical hold within that 30-day time period." This statement, combined with the timing of the Offering, lead investors to conclude that there was no clinical hold, that the IND had become effective, that clinical trials were able to commence, and that their investment would be used for clinical trials.

56. Thus, failure to disclose the FDA Communications in the Offering Documents constitutes an omission of material information necessary to make the statements in the Offering Documents not untrue and misleading, when made.

57. Disclosure of the FDA Communications was also necessary to make statements in the Offering Documents not misleading which discuss the possibility of a clinical hold as something that "may" or "could" occur, not something that Kiromic had already been informed by the FDA had occurred:

- "The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions regarding the proposed clinical trials and places the trial on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA ***may*** also impose clinical holds on a biological product candidate at any time before or during clinical trials due to safety concerns or non-compliance. ***If the FDA imposes a clinical hold***, trials may not recommence without FDA authorization and then only under terms authorized by the FDA. Accordingly, ***we cannot be sure*** that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate such trials."

- "We ***may*** also experience delays in completing planned clinical trials for a variety of reasons, including delays related to: obtaining regulatory authorization to begin a trial, if applicable. . . ."

- "Further, a clinical trial ***may*** be suspended or terminated by . . . the FDA . . . due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold. . . ."

- "The FDA's review of our data of our ongoing clinical trials ***may***, depending on the data, also result in the delay, suspension or termination of one or more clinical trials, which would also delay or prevent the initiation of our other planned clinical trials."

- "Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party suppliers or manufacturing processes, or failure to comply with regulatory requirements, ***may*** result in . . . fines, warning letters or holds on clinical trials. . ."

- "Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, ***may*** subject an applicant to administrative or judicial sanctions. FDA sanctions ***could include***, among other actions, . . . a clinical hold. . . ."

(emphasis added)

58. Discussion of a clinical hold as a mere possibility without disclosure of the FDA Communications is also untrue or misleading given that such a clinical hold had already actually occurred. While framed as cautionary language, the statements above only served to further mislead investors by communicating that a clinical hold had not been imposed. Disclosure of the FDA Communications were necessary to make these statements not untrue or misleading.

59. The failure to disclose the FDA Communications also rendered misleading the Offering Documents' disclosure relating to Kiromic's contemplated use of proceeds. The Offering Documents stated:

> We plan to use the net proceeds of this offering primarily for clinical trials for our ALEXIS-ISO-1 and ALEXIS-PRO-1 product candidates, GMP facility expansion, intellectual property protection and reinforcement, IND applications

> and IND enabling trials and working capital and the remainder for general corporate purposes.

60. This statement was misleading because the FDA had already given notice that clinical trials of the ALEXIS products were placed on clinical hold. The Offering Documents do not disclose that some of the proceeds would be needed to remedy the concerns expressed by the FDA. Moreover, many of the uses listed would not be possible unless Kiromic was able to promptly resolve the clinical hold issues with the FDA. Given that Kiromic remains subject to the clinical hold to this day, Plaintiffs believe the issues underlying the clinical hold are significant and therefore difficult, costly, or impossible to fix.

61. Moreover, the Offering Documents omitted material information that was otherwise required to be disclosed. Item 303(b)(2)(ii) of SEC Regulation S-K, 17 C.F.R. § 229.303(b)(2)(ii), required Defendants to describe in the Offering Documents "any known trends or uncertainties that have had or that are reasonably likely to have a material favorable or unfavorable impact on net sales or revenues or income from continuing operations." Similarly, Item 105 of SEC Regulation S-K, 17 CFR § 229.105, required the Offering Documents to describe "the material factors that make an investment in the registrant or offering speculative or risky." Defendants violated both Items 303 and 105 by failing to disclose the FDA Communications as a clinical hold undoubtedly constitutes an uncertainty that is reasonably likely to have a material unfavorable impact on revenues, or alternatively, a material factor which makes investment speculative or risky.

62. In addition, the Offering Documents omitted to disclose that as of June 30, 2021, Kiromic had deficiencies in its disclosure controls and procedures regarding the identification of information for disclosure during the second and third quarters of 2021. While Kiromic did

disclose that it had "identified material weaknesses in our internal control *over financial reporting*" (emphasis added), the discussion of this risk factor was specifically tailored to its financial reporting internal controls. In reality, the deficiencies in Kiromic's disclosure controls that existed at the time were far broader than its financial reporting and should have been represented as such. This represents material information that was otherwise required to be disclosed, as well as material information required to make its disclosure not misleading.

F. The Truth Emerges

63. At 2:53 PM (Eastern time) on July 16, 2021, two weeks after the closing of the Offering, Kiromic announced through a press release that it had received "comments" from the FDA regarding the ALEXIS products including "[t]racing of all reagents used in manufacturing," "[f]low chart of manufacturing processes," and "Certificate of Analysis (COA) for the Company's CAR-T products (allogeneic CAR-T)." Kiromic's common stock began a significant price decline starting at 3:01 PM (Eastern time), just eight minutes after, and as a direct result of, the July 16 press release. The stock price fell from $4.52 per share at 3:01 PM (Eastern time) on July 16 to $3.12 per shares at 4:00 PM (Eastern time), a drop of approximately 31% in less than an hour. This demonstrates that Kiromic's failure to disclose the clinical hold was material.

64. On August 13, 2021, Kiromic issued a press release which made passing reference to "clinical hold issues" but did not otherwise expand on what those issues were. The press release stated in relevant part, under the heading "Events occurring after June 30, 2021 until August 13, 2021:"

> Communications with the FDA - Supported by IQVIA, instead of simply addressing the FDA's questions with a written response only (WRO), we took the decision to apply for a Type A meeting with the FDA. The Type A meeting will address the clinical hold

> issues and will allow us to discuss path toward our first-in-human dosing.

65. A Type A meeting is a meeting needed to help an otherwise stalled product development program proceed. According to FDA guidance, it includes "[m]eetings to discuss clinical holds in which a response to hold issues has been submitted, but the FDA and the sponsor or applicant agree that the development is stalled and a new path forward should be discussed."

66. Kiromic again referenced the clinical hold in passing in another press release on October 11, 2021:

> The Company is anticipating being granted a Type A meeting with the FDA by the first half of 2022 to discuss the clinical hold and the clinical development path forward of its previously submitted IND. Following the Type A meeting, the Company plans to resubmit the investigational new drug (IND) application, and will continue to coordinate closely with the FDA to meet all regulatory requirements.

67. On February 2, 2022, Kiromic filed a Form 8-K with the SEC. Kiromic's Form 8-K disclosed that on August 17 and 23, 2021, Tony Tontat, then Chief Financial Officer, submitted reports through Kiromic's complaint hotline alleging "risks associated with the Company's public disclosures in its securities filings and in statements made to the public, investors, and potential investors regarding (i) the anticipated timing of the U.S. Food and Drug Administration's ('FDA') authorization of its investigational new drug ('IND') applications and (ii) the anticipated timing of human clinical trials."

68. Kiromic formed a Special Committee to investigate these allegations. The Special Committee established that the "Company had received communications from the FDA on June 16 and June 17, 2021, that the FDA was placing the Company's IND applications that the Company submitted to the FDA on May 14 and May 17, 2021, for the ALEXIS-PRO-1 and

ALEXIS-ISO-1 product candidates, respectively, on clinical hold." The Special Committee further found that:

> The Company did not disclose the June 16 and 17, 2021 FDA Communications in (i) its Registration Statement on Form S-1 (Registration No. 333-257427) that was filed on June 25, 2021 and declared effective on June 29, 2021, nor the final prospectus contained therein dated June 29, 2021 (collectively, the "Registration Statement"); . . .The Company consummated a public offering of $40 million of its common stock pursuant to the Registration Statement on July 2, 2021.

69. Kiromic admits that it "may be subject to claims for rescission, . . . damages, . . . or other securities law claims resulting from our failure to timely disclose" the FDA Communications. Indeed, Kiromic admits that their failure to disclose the FDA Communications could constitute misleading omissions:

> On July 2, 2021, we consummated a public offering of $40 million of our common stock. Neither the Registration Statement on Form S-1 with respect to this offering that was filed on June 25, 2021 nor the final prospectus dated June 29, 2021 with respect to this offering contained any disclosure with respect to the June 16 and 17, 2021 FDA Communications. . . . Anyone who purchased shares of our common stock in the offering and anyone who purchased or sold shares of our common stock in the public market after June 16, 2021 could claim that they were misled by our failure to disclose the clinical hold on studies under the INDs for these product candidates and that they suffered damages.

70. Moreover, Kiromic admits that "there were deficiencies in our disclosure controls and procedures over the identification of information for disclosure during our second and third quarters of 2021." In particular, Kiromic explains that "there was a deficiency in the disclosure controls and procedures in place to ensure that information related to the June 16 and 17, 2021 FDA Communications was appropriately elevated and evaluated to allow timely decisions regarding required disclosure."

71. On September 29, 2021, Tony Tontat resigned from his position as CFO. The Special Committee that investigated Mr. Tontat's allegations also found that Mr. Tontat had submitted false information regarding his educational background to Kiromic. Specifically, Mr. Tontat represented that he held a BA in Economics from Harvard University, when he actually had received an ALB, a degree conferred by the Harvard Extension School.

72. On January 27, 2022, Kiromic terminated Maurizio Chiriva-Internati as Chief Executive Officer for cause after finding evidence of "conduct that the Board believed was inconsistent with the Company's policies." The details of his conduct have not been publicly revealed.

73. Kiromic's stock has dropped steadily lower since its precipitous drop immediately following the July 16, 2021 press release. On July 19, 2022, Kiromic's stock closed at $0.38, a decline in excess of 90% from the Offering price of $ 5.00 per share. Further, had Kiromic not raised the $ 40 million with the Offering Documents which it has used to address the FDA's concerns. Kiromic's stock would be worth significantly less or could even be worthless. By way of example, Kiromic's business required approximately $25 million in cash in 2021. Without the Offering, it would not have had funds to operate. In the first quarter of 2022, approximately $10 million in funds were required. Again, without the Offering proceeds, Kiromic would not have had the financial resources to stay in business. A recent SEC filing by Kiromic advises investors that "The INDs for these trial candidates have been on a clinical hold since June 2021. We are currently working on addressing the United States Food and Drug Administration's (the "FDA's") comments. Accordingly, we expect the clinical hold on ALEXIS-PRO-1 will be lifted in the first half of 2023 allowing us to begin the activation process for the clinical trial by the end of the second quarter of 2023. For ALEXIS-ISO-1, we are targeting the activation process for the

clinical trial to begin by the end of the last quarter of 2023." There can be no doubt that without the Offering proceeds, Kiromic would not be able to operate its business for the two years needed to clear up the concerns voiced by the FDA.

COUNT I

Against Kiromic and the Individual Defendants
for Violations of Section 11 of the Securities Act

74. Plaintiffs repeat and reallege every allegation contained above.

75. This Count is brought by Plaintiffs under Section 11 of the Securities Act, 15 U.S.C. § 77k. For purposes of this Section 11 claim, Plaintiffs are not required to allege that any Defendant acted with scienter or fraudulent intent, as those are not elements of a Section 11 claim. Plaintiffs disclaim any allegations of fraud, scienter, or recklessness.

76. The Offering Documents contained untrue statements of material fact and omitted to state material facts required to be stated therein or necessary to make the statements therein not misleading, as alleged above.

77. Kiromic is the issuer for the Offering. As issuer of the shares, Kiromic is strictly liable to Plaintiffs for the misstatements and omissions in the Offering Documents.

78. As signatories of the Offering Documents, directors of the issuer, or a person performing similar functions as to a director, the Individual Defendants were responsible for their contents and dissemination.

79. The Individual Defendants did not act with reasonable care to ensure there were no untrue statements of material fact or omissions to state material facts required to be stated therein or necessary to make the statements therein not misleading in the Offering Documents.

80. These Defendants issued, caused to be issued, and participated in the issuance of materially untrue and misleading written statements to the investing public that were contained

in the Offering Documents. By reasons of the conduct alleged, each of these Defendants violated Section 11 of the Securities Act.

81. Plaintiffs' purchase of Kiromic common stock was issued pursuant to, and traceable to the Offering because Plaintiffs purchased their shares directly in the Offering.

82. Plaintiffs have sustained damages. The value of Kiromic's common stock has declined substantially after and as a result of the alleged violations.

83. At the times when it purchased Kiromic common stock, Plaintiffs were without knowledge of the facts concerning the wrongful conduct alleged in this Complaint and could not have reasonably discovered those facts before Kiromic's subsequent announcements. Less than one year has elapsed from the time when Plaintiffs discovered or reasonably could have discovered the facts upon which this Complaint is based to the time when Plaintiffs filed this Complaint. Less than three years have elapsed from the time when the securities upon which this Count is brought were bona fide offered to the public to the time when Plaintiffs filed this Complaint.

COUNT II

Against ThinkEquity for Violations of Section 11 of the Securities Act

84. Plaintiffs repeat and reallege every allegation contained above.

85. This Count is brought by Plaintiffs under Section 11 of the Securities Act, 15 U.S.C. § 77k. For purposes of this Section 11 claim, Plaintiffs are not required to allege that any Defendant acted with scienter or fraudulent intent, as those are not elements of a Section 11 claim. Plaintiffs disclaim any allegations of fraud, scienter, or recklessness.

86. The Offering Documents contained untrue statements of material fact and omitted to state material facts required to be stated therein or necessary to make the statements therein not misleading, as alleged above.

87. ThinkEquity was the underwriter for the Offering. As the underwriter, the ThinkEquity was responsible for the contents and dissemination of the Offering Documents.

88. ThinkEquity did not act with reasonable care to ensure there were no untrue statements of material fact or omissions to state material facts required to be stated therein or necessary to make the statements therein not misleading in the Offering Documents. Among other things, ThinkEquity failed to conduct adequate due diligence on the adequacy of the internal controls for Kiromic.

89. ThinkEquity issued, caused to be issued, and participated in the issuance of materially untrue and misleading written statements to the investing public that were contained in the Offering Documents, which misrepresented or failed to disclose, inter alia, the facts alleged above. By reasons of the conduct alleged, ThinkEquity violated Section 11 of the Securities Act.

90. Plaintiffs' purchase of Kiromic common stock was issued pursuant to, and traceable to the Offering because Plaintiffs purchased their shares directly in the Offering.

91. Plaintiffs have sustained damages. The value of Kiromic's common stock has declined substantially after and as a result of the alleged violations.

92. At the times when it purchased Kiromic common stock, Plaintiffs were without knowledge of the facts concerning the wrongful conduct alleged in this Complaint and could not have reasonably discovered those facts before Kiromic's subsequent announcements. Less than one year has elapsed from the time when Plaintiffs discovered or reasonably could have

discovered the facts upon which this Complaint is based to the time when Plaintiffs filed this Complaint. Less than three years have elapsed from the time when the securities upon which this Count is brought were bona fide offered to the public to the time when Plaintiffs filed this Complaint.

COUNT III

Against Kiromic for Violations of Section 12(a)(2) of the Securities Act

93. Plaintiffs repeat and reallege every allegation contained above.

94. This Count is brought by Plaintiffs under Section 12(a)(2) of the Securities Act, 15 U.S.C. § 771(a)(2). For purposes of this Section 12(a)(2) claim, Plaintiffs are not required to allege that any Defendant acted with scienter or fraudulent intent, as those are not elements of a Section 12(a)(2) claim. Plaintiff disclaims any allegations of fraud, scienter, or recklessness.

95. By means of the defective Offering Documents—which include the Prospectus—Kiromic promoted and sold Kiromic stock to Plaintiffs for its own financial interests.

96. The Offering Documents were required pursuant to a public offering and contained untrue statements of material facts, omitted to state other facts necessary to make the statements made not misleading, and omitted to state material facts required to be stated therein, as alleged above.

97. Kiromic successfully solicited the sale of its securities by participating in the preparation and distribution of the untrue and misleading Offering Documents, which included signing the Registration Statement.

98. Kiromic did not act with reasonable care to ensure there were no untrue statements of material fact or omissions to state material facts required to be stated therein or necessary to make the statements therein not misleading in the Offering Documents. In the exercise of reasonable care, Kiromic would have known of such untruth or omission.

99. Plaintiffs' purchase of Kiromic common stock was issued pursuant to, and traceable to the Offering because Plaintiffs purchased their shares directly in the Offering.

100. By reason of the conduct alleged in this Complaint, Kiromic violated Section 12(a)(2) of the Securities Act. As a direct and proximate result of such violations, Plaintiffs purchased Kiromic common stock pursuant to the Offering Documents and sustained substantial damages in connection with its purchases of the stock. Accordingly, Plaintiffs have the right to rescind and recover the consideration paid for their Kiromic shares.

101. At the times when they purchased Kiromic common stock, Plaintiffs were without knowledge of the facts concerning the wrongful conduct alleged in this Complaint and could not have reasonably discovered those facts before Kiromic's subsequent announcements. Less than three years have elapsed from the time when the securities upon which this Count is brought were sold to the public to the time of the filing of this action. Less than one year has elapsed from the time when Plaintiffs discovered or reasonably could have discovered the facts upon which this Count is based to the time of the filing of this action.

COUNT IV

Against ThinkEquity for Violations of Section 12(a)(2) of the Securities Act

102. Plaintiffs repeat and reallege every allegation contained above.

103. This Count is brought by Plaintiffs under Section 12(a)(2) of the Securities Act, 15 U.S.C. § 771(a)(2). For purposes of this Section 12(a)(2) claim, Plaintiffs are not required to allege that any Defendant acted with scienter or fraudulent intent, as those are not elements of a Section 12(a)(2) claim. Plaintiff disclaims any allegations of fraud, scienter, or recklessness.

104. By means of the defective Offering Documents—which include the Prospectus—ThinkEquity sold and passed title of Kiromic common stock to Plaintiffs for value.

105. The Offering Documents were required pursuant to a public offering and contained untrue statements of material facts, omitted to state other facts necessary to make the statements made not misleading, and omitted to state material facts required to be stated therein, as alleged above.

106. ThinkEquity did not act with reasonable care to ensure there were no untrue statements of material fact or omissions to state material facts required to be stated therein or necessary to make the statements therein not misleading in the Offering Documents. In the exercise of reasonable care, Kiromic would have known of such untruth or omission.

107. Plaintiffs' purchase of Kiromic common stock was issued pursuant to, and traceable to the Offering because Plaintiffs purchased their shares directly in the Offering.

108. By reason of the conduct alleged in this Complaint, ThinkEquity violated Section 12(a)(2) of the Securities Act. As a direct and proximate result of such violations, Plaintiffs purchased Kiromic common stock pursuant to the Offering Documents and sustained substantial damages in connection with its purchases of the stock. Accordingly, Plaintiffs have the right to rescind and recover the consideration paid for their Kiromic shares.

109. At the times when they purchased Kiromic common stock, Plaintiffs were without knowledge of the facts concerning the wrongful conduct alleged in this Complaint and could not have reasonably discovered those facts before Kiromic's subsequent announcements. Less than three years have elapsed from the time when the securities upon which this Count is brought were sold to the public to the time of the filing of this action. Less than one year has elapsed from the time when Plaintiffs discovered or reasonably could have discovered the facts upon which this Count is based to the time of the filing of this action.

COUNT V

Against the Individual Defendants for Violations of Section 15 of the Securities Act

110. Plaintiffs repeat and reallege every allegation contained above.

111. This Count is brought by Plaintiffs under Section 15 of the Securities Act, 15 U.S.C. § 77o. For the purposes of this Section 15 claim, Plaintiffs are not required to allege that any Defendant acted with scienter or fraudulent intent, as those are not elements of a Section 15 claim.

112. Each of the Individual Defendants was a control person of Kiromic by virtue of his or her position as a director or senior officer of the company, and by reason of his or her own involvement in the daily business of Kiromic. The Individual Defendants, at the time they held positions with Kiromic, were able to, and did, exercise substantial control over Kiromic's operations, including control of the materially untrue and misleading statements, omissions, and course of conduct complained of in this action.

113. Indeed, Maurizio Chiriva Internati, Gianluca Rotino, and Tony Tontat were touted in the Offering Documents as "key executives," the loss of which would impede business operations. Moreover, each of the Individual Defendants signed the Registration Statement, a necessary step in the Offering.

114. Each of the Individual Defendants exercised control over the violations of Sections 11 and 12(a)(2) of the Securities Act alleged in Counts I and II above, based on having signed the Offering Documents or having otherwise participated in the process that allowed the Offering to be completed.

115. As a result of the foregoing, Plaintiffs have suffered damages.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

A. Awarding damages to Plaintiffs for all harm sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest on the damages;

B. Awarding Plaintiffs rescission on Count II to the extent they still hold Kiromic securities, or if sold, awarding rescissionary damages in accordance with Section 12(a)(2) of the Securities Act;

C. Awarding Plaintiffs their reasonable costs and expenses incurred in this action, including attorneys' fees and expert fees; and

D. Awarding any equitable, injunctive, or other further relief that the Court may deem just and proper.

JURY DEMAND

Plaintiffs demand a trial by jury.

Dated: New York, New York
July 22, 2022

OLSHAN FROME WOLOSKY LLP

By: /s/ *Thomas J. Fleming*

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